UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,708	10/03/2003	Charlotte A. Kensil	8449-322-999	9606

20583 7590 11/07/2006

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/679,708	**Applicant(s)** KENSIL ET AL.	
	Examiner Yunsoo Kim	**Art Unit** 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or.(2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *13 October 2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *46-52,58,59 and 63-70*.
   Claim(s) withdrawn from consideration: *54,61 and 62*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 46, 49-52, 58, 59 and 63-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,146,632 (of record) as is evidenced in the specification of the instant application on p. 2-3 in view of U.S. Pat. No. 4,727,064, of record, for the reasons set forthe in the office action mailed 7/14/06.

Applicants' arguments filed 10/13/06 have been fully considered but they were not persuasive.

Applicants argue that there is no motivation to combine the references.

The '632 patent teaches a method of enhancing an immune response with an immunogenic composition comprising antigen from polypeptide, glycoprotein or lipoprotein from bacterial or viral sources (col. 3, lines 46-65, in particular) and QS-21 (col. 1, lines 3-40, col. 3, lines 26-38, Examples1-2, claims 1-8, in particular). The '632 patent further teaches the immunogenic composition can be administered to human (col. 4, lines 31-36, in particular).

In addition, the '632 patent teaches the concurrent administration of antigen and saponin adjuvant (Example 1-2, in particular).

The specification of the instant application on p.2-3 discloses that the QS-21 does not have a long shelf life, and induces irritancy and has toxic effects. As the referenced QS-21 is identical to the claimed QS-21, the referenced QS-21 also has inherent property of short shelf life and induces irritancy.

The '632 patent does not teach beta-cyclodextrin or hyroxypropyl-beta-cyclodextrin as in claims 46, 58 and 59.

However, the 064 patent teaches that the hydroxypropyl-beta-cyclodextrin (HPCD) improves solubility which reduces tendency to cause irritation. The '064 patent further teaches that the HPCD stabilizes wide range of drugs including steroid, exhibits low toxicity and extends shelf life and widely used as an excipient (e.g. additive) (col. 1, lines 25-45, col. 2, lines 36- 60, and claims 1-28, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ the HPCD as an excipient taught by the '064 patent in an immunogenic composition comprising an QS-21 and antigen as taught by the '632 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '064 patent teaches the HPCD adds stability to any drugs and extends shelf life , reduces irritation and exhibits low toxicity (col. 1, lines 25-45, col. 2, lines 36-60, and claims 1-28, in particular).

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Therefore, it is the examiner's position the combination of teachings remains obvious.

Claims 46-52, 58, 59 and 63-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,057,540 (of record) as is evidenced in the specification of the instant application on p. 2-3, 7-10 in view of U.S. Pat. No. 4,727,064, of record for the reasons set forth in the office action mailed 7/14/06.

Applicants' arguments filed 10/13/06 have been fully considered but they were not persuasive.

Applicants argue that there is no motivation to combine the references.

The '540 patent teaches a method for enhancing an immune response with an immunogenic composition comprising a peptide antigen such as gp70 and saponin adjuvant wherein the saponin can be QA-7, 17, 18, 21 and Quil-A (Examples 8-10, 12, in particular) in a human (col. 7, lines 5-6, in particular).

The '540 patent teaches a concurrent administration of antigen and saponin adjuvant (col. 7, lines 14-25 in particular) and addition of any excipient such as inert carrier (col. 8, lines 7-13, in particular).

In addition, the'540 patent teaches the saponin exhibit toxicity (col. 1, lines 31-38, example 14, in particular).

The specification of the instant application on p.2-3 discloses that the QS-21 does not have a long shelf life, and induces irritancy and has toxic effects. As the referenced QS-21 is identical to the claimed QS-21, the referenced QS-21 also has inherent property of short shelf life and induces irritancy. In addition, the referenced QA are identical to the claimed QS (p. 7-10 of the instant specification).

The '540 patent does not teach beta-cyclodextrin or hyroxypropyl-beta-cyclodextrin as in claims 46, 58 and 59.

However, the '064 patent teaches that the hydroxypropyl-beta-cyclodextrin (HPCD) improves solubility which reduces tendency to cause irritation. The '064 patent further teaches that the HPCD stabilizes wide range of drugs including steroid, exhibits low toxicity and extends shelf life and widely used as an excipient (e.g. additive) (col. 1, lines 25-45, col. 2, lines 36- 60, and claims 1-28, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ the HPCD as an excipient taught by the '064 patent in an immunogenic composition as taught by the '540 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '064 patent teaches the HPCD adds stability to any drugs and extends shelf life , reduces irritation and exhibits low toxicity (col. 1, lines 25-45, col. 2, lines 36-60, and claims 1-28, in particular).

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Therefore, it is the examiner's position the combination of teachings remains obvious.

Yunsoo Kim
Patent Examiner
Technology Center 1600
November 2, 2006

Christina Chan

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600